

STRIDESM (HMO) MEDICARE ADVANTAGE

Effective Date: 1/2016

Subject: Yervoy® (ipilimumab)

Authorization:

Prior authorization is required for all single agent and combination therapy infusions of Yervoy® (ipilimumab) administered outside inpatient settings.

Policy and Coverage Criteria:

Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Yervoy® (ipilimumab) as medically necessary for eligible adult members (18 years of age and older) when specific criteria are met.

Covered services must be:

- Reasonable and medically necessary based on the member's condition, complexity of requested service(s), and accepted standards of clinical practice;
- An essential part of active treatment of the member's medical condition, and ordered under a plan of care established and reviewed regularly by the attending physician caring for the member; and
- Furnished by provider(s) with appropriate state licensure, and accreditation/certification from an appropriate accrediting organization.

Single Agent Therapy:

Yervoy® is covered when medical record documentation confirms a diagnosis listed below, and relevant criteria are met.

Diagnosis	Criteria
<p>Unresectable or Metastatic Melanoma</p> <p>Recommended Dosage: 3 mg/kg administered intravenously over 90 minutes every 3 weeks for a total of 4 doses.</p>	<p>A single course of therapy (4 infusions) is authorized when medical record documentation confirms diagnosis and Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2.</p> <p>One additional 4 dose cycle of Yervoy® may be authorized when medical record documentation confirms diagnosis and BOTH:</p> <ol style="list-style-type: none"> 1. ECOG performance status of 0 to 2; AND 2. Clinical response to prior treatment (i.e., stable tumor regression for 3 months), and no significant side effects.
Stage III Melanoma	Treatment (administered according to FDA approved dosing

Medical Review Criteria

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Harvard Pilgrim StrideSM (HMO) policies are based on medical science and relevant information including current Medicare coverage (including National and Local Coverage Determinations), Harvard Pilgrim medical policies, and Harvard Pilgrim StrideSM (HMO) Medicare Advantage Plan materials. These policies are intended to provide benefit coverage information and guidelines specific to the Harvard Pilgrim StrideSM (HMO) Medicare Advantage Plan. Providers are responsible for reviewing the CMS Medicare Coverage Center guidance; in the event that there is a conflict between this document and the CMS Medicare Coverage Center guidance, the CMS Medicare Coverage Center guidance will control.

Diagnosis	Criteria
	<p>regimen) is authorized <u>for up to one year</u> when medical record documentation confirms diagnosis, and history of complete resection and lymphadenectomy.</p> <p>Additional doses may be authorized when medical record documentation confirms no disease recurrence AND acceptable levels of toxicity.</p>

Combination Therapy

Up to 4 doses of combination therapy (with Yervoy® and Opdivo®) are authorized when medical record documentation confirms a diagnosis of Unresectable or Metastatic Melanoma, and ALL the following criteria are met:

1. ECOG performance status of 0 to 2;
2. Combination therapy (with Yervoy® and Opdivo®) to be used as first-line therapy (i.e., initial treatment), or secondary therapy following disease progression;
3. Member is treatment naïve to PD-1 agents (e.g. Keytruda [pembrolizumab]).

Exclusions:

Harvard Pilgrim Health Care (HPHC) does not cover Yervoy® for diseases and conditions other than those listed above including, but not limited to:

- Colon cancer
- Glioblastoma
- Metastatic hormone-refractory prostate cancer
- Non-Hodgkin's lymphoma
- Non-small cell lung cancer
- Pancreatic cancer
- Prostate cancer
- Renal carcinoma
- Sarcoma
- Small cell lung cancer

Coding:

Codes are listed below for informational purposes. The list may not be all-inclusive, and does not imply or guarantee coverage or provider reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Harvard Pilgrim policies apply.

HCPCS Codes	Description
J9228	Injection, ipilimumab, 1mg

References:

1. Prescribing Information- Yervoy: Bristol-Myers Squibb Company; Princeton, NJ 08543 USA (Revised 10/15)
2. Shoushtari, AN., Charen, AS., Postow, M., Wolchok, J. Principles of cancer immunotherapy. In: UpToDate, Post, TS (ed), Waltham, MA, 2015.

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3. Sosman, JA. Immunotherapy of advanced melanoma with immune checkpoint inhibition. In: UpToDate, Post, TS (ed), Waltham, MA, 2015.
4. Postow MA, Chesney J, Pavlick AC, et al. Nivolumab and ipilimumab versus ipilimumab in untreated melanoma. N Engl J Med. 2015; 372:2006-2017.

Summary of Changes

Date	Change
5/17	References updated
8/24/16	Annual review/update. Update references. Minor language changes.
3/16	Added criteria for stage III melanoma and combination therapy with Opdivo. Updated criteria for combination therapy with Opdivo based on FDA approvals. Update references.

Approved by UMPCP: 5/10/17
Reviewed/Revised: 3/16; 8/16; 5/17
Initiated: 1/1/16

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